## ORDER DENYING THE PETITION FOR REHEARING
**(Filed September 30, 1982)**

**No. 81-5227**

**UNITED STATES COURT OF APPEALS**
**FOR THE NINTH CIRCUIT**

Pfizer, Inc.

*Plaintiff-Appellee*

vs.

International Rectifier Corporation, Rachelle Laboratories Italia, S.p.A., Rachelle Laboratories, Inc., and Rachelle Pharmaceuticals International, S.A.

*Defendants-Appellants.*

Before: Ely, Goodwin and Wallace, Circuit Judges

The Petition for rehearing is denied.

**OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT**
**(Filed August 26, 1932)**

**No. 81-5227**

**UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT**

Pfizer, Inc.

*Plaintiff-Appellee*

vs.

International Rectifier Corporation, Rachelle Laboratories Italia, S.p.A., Rachelle Laboratories, Inc., and Rachelle Pharmaceuticals International, S.A.

*Defendants-Appellants.*

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**APPEAL FROM UNITED STATES DISTRICT COURT FOR THE CENTRAL DISTRICT OF CALIFORNIA**

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Martin Pence, District Judge, Presiding
Argued and Submitted August 4, 1982

Before: ELY, GOODWIN, and WALLACE, Circuit Judges

ELY, CIRCUIT JUDGE:

Essentially upon the basis of the findings of fact and the carefully reasoned opinion of the District Judge, reported at F. Supp. , 207 U.S.P.Q. 397 (C.D. Cal. 1980), we affirm the judgment upholding the validity of Pfizer's Patent No. 3,200,149.

A word here is proper, however, concerning the scope of the concept of materiality in determinations of whether a party's withholding of information from the Patent Office constitutes a fraud or inequitable conduct sufficient to operate as a bar to a claim of infringement. The parties vigorously

dispute the proper standard of materiality as enunciated by this Court in prior cases. At oral argument the appellants asserted that the District Court's opinion was contrary to three controlling Ninth Circuit decisions that address the issue of fraud before the Patent Office. *See W. R. Grace & Co., Inc. v. Western U.S. Industries, Inc.*, 608 F.2d 1214, 1218 (9th Cir. 1979), *cert. denied*, 446 U.S. 953 (1980); *Maurice A. Garbell, Inc. v. Boeing Co.*, 546 F.2d 297 (9th Cir. 1976), *cert. denied*, 431 U.S. 955 (1977); *Monolith Portland Midwest Co. v. Kaiser Aluminum & Chemical Corp.*, 407 F.2d 288 (9th Cir. 1969). We do not agree. The District Court's opinion is consistent with the standards announced in those cases.

In judging whether misrepresentations made before the Patent Office rise to the level of fraud or inequitable conduct that would justify invocation of the maxim of unclean hands, we have not adopted, as the appellants argue, a definition of materiality that encompasses any information that "might affect" the patentability of the claimed invention. Rather, we have adhered to the proposition that false statements or omissions are material so as to constitute fraud before the Patent Office when such statements or omissions were a "*substantial cause*" of the patent grant or a "*crucial factor*" in obtaining the patent. *See W. R. Grace & Co., Inc.*, 608 F.2d at 1218; *Cataphote Corporation v. DeSoto Chemical Coatings, Inc.*, 450 F.2d 769, 773 (9th Cir. 1971), *cert. denied*, 408 U.S. 929 (1972); *Monolith Portland Midwest Co.*, 407 F.2d at 296. The proper focus in determining the materiality of information misrepresented to or withheld from the Patent Office is on the *effect* of the misrepresentation or withholding upon the subjective considerations of the patent examiner. *See Norton v. Curtiss*, 433 F.2d 779, 795 (C.C.P.A. 1970).

The appellants have cited and relied on language in our cases that a patent applicant has a duty to disclose "all facts which may affect the patentability of his invention." *Monolith*, 407 F.2d at 294; *see Maurice A. Garbell, Inc. v. Boeing Co.*, 546 F.2d 297, 300 (9th Cir. 1976), *cert. denied*, 431 U.S. 955 (1977). This standard is inapposite to a determination of the *materiality* of false statements or omissions before the Patent Office; rather, the *Monolith* language bears on another requisite element of fraud—that of state of mind, or scienter. *See W. R.*

*Grace & Co., Inc.*, 608 F.2d at 1218. An inquiry into whether withheld information "may affect" the patentability of an invention must be distinguished from a determination of the actual impact of omitted information upon a patent examiner's decisions. The former is an inquiry into the state of mind of the applicant at the time the decision to withhold is made; the latter is an inquiry into the materiality of the information withheld.

In addition to materiality, a party seeking to invalidate a patent by invocation of the doctrine of unclean hands must establish a sufficiently culpable state of mind on the part of the patent applicant. *Carpet Seaming Tape Licensing Corp. v. Best Seam Incorporated*, 616 F.2d 1133, 1138-39 (9th Cir. 1980). We have stated that only a showing of wrongfulness, willfulness, bad faith, or gross negligence, proved by clear and convincing evidence, will establish sufficient culpability for invocation of the doctrine of unclean hands. *See Carpet Seaming Tape Licensing Corp.*, 616 F.2d at 1138-39; *W. R. Grace & Co., Inc.*, 608 F.2d at 1218 (standard established if plaintiff's course of conduct "reveals a calculated recklessness about the truth").

The District Court's opinion in this case was consistent with these standards. It found that the appellants failed to show by clear and convincing evidence that Pfizer misrepresented or concealed prior art, facts, or information material or pertinent to patentability. See F. Supp. at , 207 U.S.P.Q. at 437. In making this determination the District Court properly relied on the patent examiner's testimony that he was not misled by Pfizer's representations, *id.* at , 207 U.S.P.Q. at 408, 430, and that certain information Pfizer withheld "would not have made any difference" to the patent examiner's decision, *id.* at , 207 U.S.P.Q. at 430. The evidence clearly supports a finding that the information withheld by Pfizer was not a crucial factor or a substantial cause of the patent grant and, therefore, the District Court's conclusion that the information was not material is not error.

AFFIRMED.

# EXCERPTS FROM THE CORRECTED DECISION OF THE UNITED STATES DISTRICT COURT FOR THE CENTRAL DISTRICT OF CALIFORNIA
**(Filed June 12, 1980)**

**No. 73-58**

## UNITED STATES DISTRICT COURT FOR THE CENTRAL DISTRICT OF CALIFORNIA

Pfizer,[1] Inc.

*Plaintiff-Appellee*

vs.

International Rectifier Corporation, Rachelle Laboratories Italia, S.p.A., Rachelle Laboratories, Inc., and Rachelle Pharmaceuticals International, S.A.

*Defendants-Appellants.*

## ("CORRECTED"*) DECISION

On May 5, 1961 Application Ser. No. 106,146 was filed in the United States Patent Office as a continuation in part (c.i.p.) of a prior co-pending Application Ser. No. 31,236 as filed May 23, 1960. The application listed Robert E. Blackwood, Hans H. Rennhard, John J. Beereboom, and Charles R. Stephens, Jr., inventors, as assignors to Charles R. Pfizer & Co., Inc. of New York, N.Y., a Delaware corporation. The application was for a patent on 6-deoxytetracycline derivatives and process. It was not until over five years later, on August 10, 1965, that Patent #3,200,149 was issued on certain chemical processes and products, one of which was the chemical compound that came to be known as alpha-6-deoxy-5-oxytetracycline. The generic name for that compound is doxycycline, marketed by Pfizer under the trademarked name of Vibramycin.

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[1] The corporate name was subsequently changed to Pfizer, Inc.

* After this court's decision was filed, a number of typographical, et al, errors were noted by counsel. This "court-corrected decision" does but eliminate those errors. The changes are not essential.

Doxycycline, a synthetically produced chemical of the tetracycline family, proved to be a broad spectrum antibiotic exhibiting a high order of antibacterial action against a wide range of disease-causing microorganisms. It had essentially the same antibacterial properties of the fermentation-produced tetracyclines but had antibacterial action (microbiological activity against gram-positive and gram-negati/e microorganisms) superior to that of any other then known 6-deoxytetracyclines. As appeared in the file wrapper of the patent, it took a smaller amount of doxycycline to secure the antibacterial action expected from any of the then known tetracyclines. Because it took a smaller dosage to produce like antibiotic effects, a patient taking doxycycline did not have to take as many or as large dosages of a tetracycline drug as had been necessary before. Although it was *not* set forth in the patent application as one of the properties of the drug, doxycycline was found to have a lipophilicity much greater than any tetracycline and could be used much more freely by persons with renal diseases. Doxycycline became one of the msot commercially successful of the tetracycline group of antibiotic drugs.

International Rectifier Corporation (IR), with head office in California,[2] began making doxycycline in Italy using the process described in Pfizer's patent, and started selling and distributing it in the United States and elsewhere in 1973, at a price very much lower than that charged by Pfizer. Pfizer then brought the patent infringement suit now before the court, seeking damages and declaratory and injunctive relief, in the Central District of California, against IR, as well as U.S.V. Pharmaceutical Corporation, which had distributed IR's doxycycline[3] in the United States.

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[2] International Rectifier Corporation had 4 subsidiaries: Rachelle Laboratories Italia S.p.A. of Italy; Rachelle Laboratories, Inc., with its principal place of business in Los Angeles County, California; Rachell Pharmaceuticals International, S.A. of Brussels, Belgium; and Rachelle Laboratories (Philippines), Inc. Rachelle Italia is no longer in existence.

[3] IR's trade name was Doxychel

As is standard procedure in almost every patent infringement action, IR and USV answered that Pfizer's patent was invalid and unenforceable for failure to meet statutory requirements of patentability and for fraud and misconduct before the Patent Office. Both defendants at first admitted infringement but thereafter moved to amend their answers, asserting unfair competition and antitrust counterclaims, as well as denying infringement. (This court subsequently refused to allow them to amend to deny infringement.) Upon defendants' motion, and because the so-called "Antibiotics Antitrust Litigation"[4] was already pending there, the Judicial Panel on Multidistrict Litigation, in March 1973, transferred the case to District Judge Miles W. Lord in the District of Minnesota.

During pretrial action before Judge Lord, defendants moved for partial summary judgment, claiming that Pfizer's conduct during the processing of the patent constituted fraud, inequitable conduct, and unclean hands, and, in addition, charged that Pfizer's conduct before Judge Lord between 1973 and 1975 was also fraudulent and inequitable and separately justified invalidation of the patent.

On July 16, 1975, Judge Lord granted partial summary judgment against Pfizer on both grounds and declared that its doxycycline patent was invalid and unenforceable.[5]

Pfizer appealed, and on June 16, 1976, the Appellate Court reversed Judge Lord, 538 F. 2d 180 (8th Cir. 1976), holding that the evidence presented as to alleged misconduct of Pfizer before the Patent Office showed the existence of such material issues of fact as to preclude summary judgment. The Appellate Court further held that Judge Lord's findings that Pfizer had practiced fraud and other inequitable conduct upon the court were clearly erroneous. The case was then remanded for completion of pretrial proceedings to be followed by a plenary trial.

This judge was requested by both plaintiff and defendants to try the case, jury-waived, and, with the consent of Judge

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[4] This litigation was concerned with the fermentation-produced tetracyclines.

[5] Pfizer, Inc. v. International Rectifier, 186 U.S.P.Q. 511, D.Minn. 1975.

Lord he took over the case. Upon motion, the Judicial Panel transferred it back to the Central District of California. Then followed further extensive pretrial proceedings, during which USV reached an agreement with Pfizer and withdrew from the case.[6] Trial on the issue of validity and all issues relating to enforceability which involved claims of fraud or inequitable conduct in the Patent Office was started on October 15, 1978 before this judge, sitting in the Central District of California, and continued almost uninterruptedly until March 8, 1979. The trial produced over 6,000 pages of transcript, over 2,000 exhibits, and almost a "ten-foot shelf" of depositions. Post-trial Briefs and Answering Post-trial Briefs were also filed by both plaintiff and defendants.[7] The mass of evidence produced at trial more than proved the soundness of the conclusion of the 8th Circuit that there were such material disputed issues of facts as to preclude summary judgment. Disputed issues of intent, good faith, credibility, and other subjective feelings, all of which are entwined in any claim of fraud or inequitable conduct before the Patent Office, demanded full examination through a plenary trial.

Although this case was tried in the 9th Circuit, nevertheless this court feels that the statements of the Court of Appeals for the 8th Circuit regarding the law of the case approach the level of stare decises, if not res adjudicata. As pointed out by the 8th Circuit:

> The principle that a defendant in a patent infringement action may interpose as a complete defense the patentee's failure to deal candidly with the Patent Office is a corollary of the equitable doctrine of unclean hands. The Supreme Court has set forth the duty of candor owed by a patent applicant as follows:

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[6] IR immediately amended its answer to charge USV and Pfizer as having engaged in an unlawful conspiracy, etc. USV and IR, however, subsequently settled that claim.

[7] Counsel on each side proved to be highly competent attorneys, exceptionally well versed in chemical patent litigation, and the interests of their respective clients were well protected on the record. All issues were unstintingly and bitterly contested.

> Those who have applications pending with the Patent Office or who are parties to Patent Office proceedings have an uncompromising duty to report to it all facts concerning possible fraud or inequitableness underlying the applications in issue. * * * Public interest demands that all facts relevant to such matters be submitted formally or informally to the Patent Office, which can then pass upon the sufficiency of the evidence. Only in this way can the agency act to safeguard the public in the first instance against fraudulent patent monopolies.
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> *Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806, 818 (1945).

The equitable origins of this doctrine, combined with recognition of the growing administrative burden facing the Patent Office, have led to expansion of the defense in recent years to encompass also a wide variety of inequitable conduct short of common law fraud or deceit. (558 F.2d 180, 185)

* * * [T]he standard [of conduct] is not one of strict liability for innocent or even negligent omissions or misstatements before the Patent Office. Rather, to result in refusal to enforce a patent, the misconduct must be accompanied by "some element of wrongfulness, willfulness, or bad faith" (a "willful act * * * which rightfully can be said to transgress equitable standards of conduct"). This requirement of proof has been uniformly applied in infringement actions be a majority of the circuits to claims of both fraud and lesser inequitable conduct. Moreover, proof of misconduct under either theory must be established by "clear, unequivocal and convincing" evidence. (185, 187, supra)

[portions of the text omitted]

## II. RUTHENIUM AS A CATALYST

IR next maintains that Pfizer fraudulently claimed the use of ruthenium as a catalyst for preparing doxycycline. Pfizer's application stated on page 3: (24)

> The noble metal catalysts as employed in the present invention include platinum, palladium, rhenium, rhodium and ruthenium, as well as the known catalytic compounds thereof such as the oxides, chlorides, etc. . . . Examples of preferred catalysts are 5% palladium-on-carbon, 5% platinum-on-carbon, 5% rhodium-on-carbon, platinum chloride, palladium chloride, platinum oxide and ruthenium oxide . . .

Thereafter on page 4 appears:

> Rhodium is the preferred catalyst for the process of the present invention since it produces the highest overall yield of 6-epi-6-deoxy [alpha-6-deoxy] and 6-deoxytetracyclines [beta-6-deoxytetracyclines] the other noble metal catalysts are entirely operative to obtain both 6-epi-6-deoxy and 6-deoxytetracyclines.

On page 10 appears:

> In summary of the process of the present invention, it will be appreciated that it not only provides a convenient means for producing new and useful 6-epi-6-deoxytetracyclines but in addition, also produces known 6-deoxytetracyclines. Whereas the latter compounds may be produced by hydrogenation of a parent tetracycline antibiotic, i.e., one containing both a 6-methyl and a 6-hydroxy substituent, the procedure of the present invention is preferred since the yields thereof are substantially higher than those obtained by the known procedure.

IR maintains that:

> Blackwood, Stephens, Rennhard, Beereboom and von Schach . . . knew that they had been unsuccessful in using ruthenium as a catalyst for the methacycline hydrogenation process in six attempts over a more than seven months period prior to the filing of the doxycycline application and in seven additional attempts over a year-and-a-half period during the pendency of the application. (25)

The thrust of IR's argument is that Pfizer knew that ruthenium would not work as a catalyst but nevertheless included ruthenium in its application to prevent others from using it. Even this illogical approach, however, is not borne out by the evidence of the 13 early Pfizer experiments using ruthenium as a catalyst. Contemporaneous notebook entries of six experiments show that ruthenium catalyzed the reaction and five show that either beta or alpha 6-deoxy tetracycline was formed and on the papergrams of another ruthenium-catalyzed hydrogenation a spot was found in the doxycycline region. (26)

In his January 1961 monthly report, Dr. von Schach reported, "Although the results are not quite as clear cut as stated, we found that palladium and ruthenium catalyzed the hydrogenation of the double bond very slowly." (27) A detailed experiment-by-experiment analysis of the evidence on those referred to by IR as having failed (the contents of which are as set forth by Pfizer in its Post Trial Brief, pp. 129-133) does not permit the conclusion that ruthenium could not be used as a catalyst as claimed. This court concludes that Beereboom's monthly report of September 25, 1961, (28) stating that ruthenium will not work under the conditions used, was not intended to indicate that it could *not* work but that ruthenium did not produce commercially satisfactory yields. (29) This court reaches the same conclusion concerning Dr. Beereboom's and Dr. von Schach's joint report of December 18, 1961. (30) It, too, concerned itself with "the most practical synthetic routes to GS 3065" (doxycycline) and "concerned itself with the commercial preparation" of doxycycline. (31) The statement in that report that "catalysts such as ruthenium and Raney nickel . . . have failed to give the desired reaction" was intended to refer to the efficient production of larger quantities of doxycycline. This court accepts as true Dr. von Schach's statement that if that report were to be interpreted as stating that ruthenium had failed to catalyze the reaction and produce doxycycline, then such interpretation would be "clearly inaccurate". (32) This court finds that ruthenium could and would catalyze the reactions as claimed.

To confirm Pfizer's reference to the use of ruthenium was Dr. Murai's report that "a reasonable quantity of 6-(alpha)-

desoxytetracycline (0.3g) has been isolated from crude hydrogenation product of GS2330 (309)." (33) Ruthenium was the catalyst used in that hydrogenation. The only references in the patent showing yields of doxycycline are found in Examples 32 and 33 and both of those examples specifically recite the use of rhodium as the catalyst, which the patent explicitly stated was the preferred catalyst.

Nowhere in the file wrapper could this court find that Pfizer had made any representation regarding the yield of doxycycline if ruthenium was used as a catalyst. Examiner Adams was questioned in reference to the above-quoted sentence in the patent application beginning, "Rhodium is the preferred catalyst", et cetera: "Q. From reading the application during the time you were with the Patent Office, did you understand that ruthenium would also produce high yields of doxycycline?", Adams replied, "No." (34) He further testified that he would have understood from the application "that you could produce 6-epi and 6-deoxy tetracycline with the ruthenium catalyst in at least recoverable amounts, useful amounts." (35)

In the cross examination of Examiner Adams by IR's counsel Cohen, in response to the question: "[A]ssuming that *all* of Pfizer's experiments using ruthenium as a catalyst had failed to produce *any* alpha-6-deoxytetracycline", Adams stated that he would have rejected the process claims which included ruthenium as a catalyst. Upon re-direct examination, he was asked:

> Q. Now, I would like you to assume this set of facts:
>
> I would like you to assume that applicant's assignee and the applicant had conducted various experiments hydrogenating materials specified in the process claims of the doxycycline application, using ruthenium as the catalyst, under various conditions.
>
> I would like you to assume further that, under some reaction conditions, there did not appear to be evidence that the starting material was successfully hydrogenated.

Assume further that in other instances, within the scope of the process claims ruthenium did catalyze the reaction.

And assume that in some instances there was evidence that 6-epi-6-deoxytetracyclines were produced, including doxycycline.

Lastly assume that the applicant and applicant's assignee believed, based upon their knowledge and experience in the tetracycline art, that ruthenium would catalyze the hydrogenation, and that 6-epi-6-deoxy-tetracyclines, including doxycycline, would be produced thereby.

Now, if you had rejected claims 1, 4, 5 and 8 for inoperability and these facts were established in response to your rejection, would you have maintained the rejection?

* * * *

A. No. On the facts that they have stated, they have shown that ruthenium can catalyze the reaction, and they continued to believe that it can. (36)

Adams further testified:

Q. Mr. Adams, what was your view during the time of the prosecution of the doxycycline patent application regarding whether an applicant had an obligation to call to the attention of the Patent Office experimental failures if the applicant had a reasonable basis to believe the invention, as claimed, was operable and could be practiced through use of ordinary knowledge and skill in the art?

A. My view was he had no obligation to call such failures to the attention of the Patent Office.

Q. And what was your view regarding whether an applicant, who had experienced experimental fail-

ures, had to conduct successful experiments before he could claim the subject matter?

A. My view, then as now, is that there is no requirement to conduct any experiments, successful or otherwise, in order to obtain a patent application. That is it.

MR. COHEN: May I hear that question and answer, please.

(A portion of the record was read back by the reporter.)

Q. What do you mean by "to obtain a patent application?"

A. Should be "to obtain a patent." (37)

**Conclusion**

IR has failed to sustain its burden of proving its claim that Pfizer fraudulently claimed the use of ruthenium as a catalyst for preparing doxycycline by "clear, unequivocal and convincing evidence".

## III. THE EXAMPLE 35 PROCESS

In connection with its claim of inoperability, IR maintained that Pfizer fraudulently claimed the Example 35 process for making 7-chloro doxycycline. Example 35 teaches the preparation of 7-chloro doxycycline (7-chloro-6-epi-6-deoxy-5-oxytetracycline) by hydrogenating 7-chloro methacycline (7-chloro-6-deoxy-6-damethyl-6-methylene-5-oxytetracycline). IR maintains that *all* of Pfizer's 25 experiments failed to make 7-chloro doxycycline by the Example 35 process or by analogous processes which should have also produced some 7-chloro doxycycline. IR points out that Beereboom's monthly reports of April and May 1961 state that "all attempts and efforts" to produce 7-chloro doxycycline by the Example 35 techniques were unsuccessful. (38) IR maintains that Pfizer had the duty to disclose its failure and any excuses therefore to the Patent Office. IR also maintains that Pfizer *knew* that the 7-chloro group in the tetracycline molecule was highly susceptible to

removal upon catalytic hydrogenation, but that Pfizer, with such knowledge, nevertheless retained Example 35 in the doxycycline application and issued claims embracing the Example 35 process for making 7-chloro doxycycline without disclosing those facts or its experimental failures to the Examiner. IR then maintains that Pfizer had no factual basis for a good faith belief that Example 35 worked. IR maintains that Pfizer's conduct in not presenting the facts of its failure to make 7-chloro doxycycline by Example 35 technique constitutes fraud upon and inequitable conduct before the Patent Office.

While IR lists 25 hydrogenations of 7-chloro methacycline which it claims failed to make 7-chloro-doxycycline, a detailed analysis of those experiments shows that most of them employed palladium catalyst which is not recommended for retention of the 7-chloro substituent. In all but one of the rhodium-catalyzed hydrogenations cited residual sulpher in the starting material poisoned the catalyst thus defeating the hydrogenation. (39) The purpose of Dr. von Schach's hydrogenations were specifically designed to produce methacycline by *removing* the 7-chloro substituent. (40) Dr. von Schach did not attempt to make 7-chloro doxycycline in any of those experiments. (41) In his November-December 1963 bimonthly report (one of three consecutive reports; IR 775-776-777), he reported several possibilities for the preparation of labeled GS 2876 were explored (see p. 147, Pfizer's PT3). Dr. Beereboom testified that a review of his early notebooks and monthly reports satisfied him that his experiments had produced indication of the formation of 7-chloro doxycycline. (42) Three of those experiments involved the hydrogenation of 7-chloro methacycline (GS2829) and the others involved hydrogenation fo 7, 11a-dichloro methacycline (GS2988) (both processes are disclosed in the doxycycline patent). (43) Although IR maintained that the hydrogenation of GS 2988 was "not an issue in this case" since the patent Example 35 starts with GS 2989, Dr. Beereboom testified:

> [I]t was well established that the first thing that would happen in the hydrogenation of GS 2988 would be

> the generation of GS 2989. So from the practical standpoint while I was conducting these experiments and it is my belief today the hydrogenation of 2938 is equivalent to the hydrogenation of 2989. (44)

It is to be noted that Patent Example 6B stops the hydrogenation of GS 2988 at the point where the 11a-chloro group has been removed and isolates GS 2989. Thus, as Dr. Blackwood testified, (45) the hydrogenation of GS2988 to 7-chloro doxycycline proceeds via the hydrogenation of GS2909. As Dr. Beereboom testified, he fully expected 7-chloro doxycycline to be formed by the process set forth in Example 35.

This court is satisfied that Pfizer's chemists had produced 7-chloro doxycycline by that method.

IR has placed great emphasis on statements made by Examiner Adams in the course of his examination by IR's counsel during deposition discovery. (46) IR's questions to Adams asked that he assume that Pfizer's Claims I, II, and IV included hydrogenating 7-chloro methacycline to make 7-chloro doxycycline, and that all of Pfizer's experiments thereon failed. Based upon that assumption, Adams testified that if Pfizer did not demonstrate it had in fact succeeded in preparing 7-chloro doxycycline by the Example 35 technique or demonstrate a factual basis for a good faith belief that 7-chloro doxycycline could be thus prepared, he would have made that rejection final. As indicated heretofore, Pfizer has satisfied this court that it had a factual basis for a "good faith" belief that 7-chloro doxycycline could be prepared by the Example 35 technique, and that it had in fact succeeded in so preparing it.

Even if this were not so, Examiner Adams thereafter testified that it is not necessary for an applicant to actually have produced a product or performed a process in order to claim it. He said,

> My understanding, at the time I was in the Office, at the time—at the present time, is that there is no requirement under U.S. Law for a patent applicant to have ever done anything in the laboratory to claim either a chemical process or a chemical product. 35 USC 112 requires only

that the applicant describe his invention and teach how to make and use the same. If an applicant believes that, in "carrying out a chemical process—in good faith believes that, in carrying out a chemical process, a certain result will follow and claims that process and/or the results that follow, to my knowledge, that is all that is required in order for him to file an application."

He continued,

> If, in spite of failure to make 7-halo, Pfizer scientists were still of a good-faith belief that the 7-halo derivative could be made by processes that they have described, then I think that would have been a—certainly a proper basis for them to have claimed the subject matter, and it also would have been a response to a rejection made.

* * * *

> . . . [T]he question I would have raised: [is] inoperability. And if the applicant comes back and says, "You are wrong. It works," then that is an adequate response. (47)

Underlying IR's charges of fraud or inequitable conduct in both the preceding ruthenium and this Example 35 issues is its claim that Pfizer had absolute duty to call the Examiner's attention to each and every failure. The 8th Circuit, in its opinion preceding this trial,[8] stated:

> In the instant case, the District Court adopted a far-reaching interpretation of the doctrine (that parties to a Patent Office proceeding have an *uncompromising duty* to report to it all facts concerning possible fraud or inequitableness underlying the application) emanating from what the court described as an obligation on Pfizer's part to disclose to the Patent Office any fact that "may be relevant to an issue of patentability." Further, the court held that the defendants in proving Pfizer's breach of this obligation were not required to prove that Pfizer intended to deceive the patent examiners, and that Pfizer's claims of good faith are immaterial and do not create genuine issues of fact. We believe this interpretation imposes an unwork-

[8] Pfizer, Inc., v. IR Corp., 538 F.2d 180, 185, supra.

> able standard of conduct upon the patent applicant and expands the inequitable conduct defense beyond legitimate limits . . . to result in refusal to enforce a patent, the misconduct must be accompanied by "some element of wrongfulness, willfulness, or bad faith" . . . .

This court finds nothing arising out of the fact that Pfizer did not advise the Patent Office of *all* of its experiments, good or bad, involving either ruthenium or Example 35 that manifested any element of wrongfulness, willfulness, or bad faith required for patent invalidation.

IR has failed to sustain its burden of proving its claim that Pfizer fraudulently claimed the Example 35 process for making 7-chloro doxycycline by "clear, unequivocal and convincing" evidence.

[portions of the text omitted]

## VII. ANTIBACTERIAL ACTIVITY OF DOXYCYCLINE

While it is now known that doxycycline is a superior broad spectrum antibiotic exhibiting a wide order of antibacterial activity against a wide range of disease-causing microorganisms,[9] nevertheless IR maintains that Pfizer fraudulently misrepresented the antibacterial activity of doxycycline. It is IR's "position that, in documenting the superior activity of doxycycline as compared with the McCormick compound, Pfizer deliberately exaggerated doxycycline's antibacterial activity in every conceivable way, thereby precluding the patent examiners from fairly evaluating the relative activities of the respective compounds." (195) IR further maintains that these exaggerations were deliberately aimed at forging "the chain binding the examiners to Pfizer's non-obviousness argument." (196) IR points out that during the prosecution Pfizer "harped upon the substantial 'differences in properties', (197) the 'differences in kind', (198) and the 'differences of approximately 36-fold' ". (199)

The file wrapper shows that Examiner Berg in 1962 had withdrawn his prior rejection of Pfizer's claims upon receipt of

[9] See "Background", pages 1-2.

the English and McBride affidavits concerning the antibacterial activity of doxycycline stating that the affidavits "had been carefully considered and are deemed persuasive in overcoming the rejection." (200)

Even though the file wrapper on its face negates IR's claim that the patent Examiners were deliberately misled by the English and McBride affidavits of antibacterial activity into granting Pfizer's claims, IR insists that Pfizer fraudulently exaggerated and magnified the "showing of antibacterial activity in an effort to dramatize its claim of unexpected and unobvious advantage." (201) The focal point of IR's attack is its claim that by disclosing this doxycycline was active in vitro against staph 400, thereby Pfizer suggested its possible activity in vivo against strains that were resistant to tetracycline. IR claims that by simultaneously withholding doxycycline's inactivity in vivo against staph 400, then and thereby Pfizer misrepresented doxycycline's antibacterial activity.

Pfizer's Dr. Von Schach stated that Pfizer's scientists regarded the demonstration of in vitro activity of a prospective antibacterial compound as indicating the possibility of in vivo activity. (202) Dr. English testified that he believed that an indication of in vitro activity against the tetracycline resistant strain warranted further work to determine whether the compound additionally exhibited in vivo activity against the same strain. (203) Pfizer's scientists tested doxycycline against staph 400. IR's thesis is that since Pfizer's scientists found, and it was so reported to the Examiner, that doxycycline showed activity against staph 400 in vitro, while Pfizer's report to the Patent Office did *not* state that its tests in vivo had *not* shown antibacterial activity, ergo Pfizer deliberately misled the Examiners into inferring that it was in fact potentially active in vivo. Although IR's argument has an abstract plausibility, nowhere in the record is there any indication that any of the Examiners, inferentially or otherwise, were led to believe that doxycycline was active in vivo against staph 400. The English and McBride affidavits were filed to compare the activity of doxycycline with that of the prior art McCormick compound. The McCormick compound had not been tested against staph 400 in vivo. (204)

Nowhere in the record is there any representation that doxycycline was active in vivo in each and every microorganism against which it manifested an in vitro activity.

On the record, this court agrees with Dr. English: "There is no reason to believe, based on an MIC that a compound will have activity in vivo." (205) Dr. Woodward, when asked whether in vivo activity necessarily follows from in vitro activity, said: "Good Lord, no; I wish it did." (206)

Ir response to a question as to whether it was his understanding during the prosecution of the doxycycline patent that an antibiotic compound displaying substantial in vitro activity against a particular microorganism was necessarily active in vivo against the same microorganism, Adams answered: "My understanding was that you could not [necessarily] predict activity from any in vitro activities . . ." and continued to state that in passing the doxycycline patent to issue, he did not make any assumption whatsoever that doxycycline was active in vivo against each and every microorganism against which it displayed in vitro activity. Moreover, Examiner Adams gave this testimony:

> Question: Now if you had been specifically informed that doxycycline was inactive in vivo against that same staph 400, would it have made any difference to you in your decision to allow the product claims in this case?
>
> Answer: No, it would not have made any difference. (207)

In IR's Dr. Mitscher's patent application on 5a, 6-anhydrotetracyclines filed in February of 1964 and issued in 1966 states: "The novel compounds of the present invention are useful as antibacterial agents since they are biologically active and possess broad spectrum antibacterial activity." The application then represents the in vitro activity (MIC values) of several of the compounds. (208) Dr. Mitscher testified that the compounds claimed in the application had no significant in vivo activity. (209) Nowhere in Dr. Mitscher's patent application or its file wrapper is that fact disclosed.

IR admits that doxycycline "had superior in vitro antibacterial activity than the prior art (McCormick) compound" and that "doxycycline had greater antibacterial activity than the McCormick compound." (210) This court has carefully reviewed the file wrapper (211) and all of the representations made therein regarding the antibacterial activity of doxycycline, as well as the testimony relating thereto, and finds that Dr. English's affidavit did not exaggerate actually or inferentially the antibacterial activity of doxycycline in vitro. (212) This court has also again reviewed the affidavit of Dr. McBride (213) directed to doxycycline's in vivo activity, as well as the testimony regarding the same (214) and finds that while MIC values, like other biological measurements, are subject to some variation and thus not precisely reproducible they provide those skilled in the art with highly valuable information particularly for comparative purposes. (215) The McBride test demonstrated that doxycycline is a much more active antibiotic than the McCormick compound. Dr. English's 1964 test, made for the purpose of presenting Pfizer's claims to the F.D.A., did not use the same controls as Dr. McBride, but instead, Dr. English's 1964 test involved staph 5 mp (mouse-passed) and multiple dosing. (216) The purpose of mouse-passing is to render the culture more virulent and generally a higher dose of antibiotic is required to inhibit infection. Thus, Dr. English's data based on mouse-passed cultures is not valid comparison with data derived from non-mouse-passed cultures. (217) Both Dr. McBride's 1961 test and Dr. English's 1964 test demonstrate that doxycycline is in fact vastly superior to the McCormick compound both in vitro and in vivo.

If more were needed to indicate that IR has failed to carry out its burden of proof, Examiner Adams testified that he did not rely on the affidavits of either English or McBride in deciding to issue the patent:

> With LeGrice and Brown, the requirement for a reference was it had to be enabling. There was no reference known to me . . . which taught how to make the 6-epi 6-deoxy tetracyclines . . . [therefore] they were

> unobvious . . . There was no prima facie case of obviousness and therefore no requirement for the applicant to show superiority over any known compounds.

Adams also testified that a showing that doxycycline was 8 to 10 times more active than the McCormick compound would have been more than sufficient to establish nonobviousness. (219)

IR has failed to fulfill its burden of proving that Pfizer's actions in any way fraudulently misrepresented the antibacterial activity of doxycycline or that Pfizer failed to fulfill its duty of full disclosure and absolute candor to the Examiners.

[portions of the text omitted]

Pfizer's patent #3,200,149 is VALID.

Plaintiff's counsel will prepare the partial judgment.

DATED: Honolulu, Hawaii, June 6, 1980

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UNITED STATES DISTRICT JUDGE

## CODE OF FEDERAL REGULATIONS (PATENT OFFICE RULES), 37 CFR 1.56(a)

**§1.56 Duty of disclosure; striking of applications.**

(a) A duty of candor and good faith toward the Patent and Trademark Office rests on the inventor, on each attorney or agent who prepares or prosecutes the application and on every other individual who is substantively involved in the preparation or prosecution of the appliction and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application. All such individuals have a duty to disclose to the Office information they are aware of which is material to the examination of the application. Such information is material where there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent. The duty is commensurate with the degree of involvement in the preparation or prosecution of the application.

[42 FR 5593, Jan. 28, 1977]

## MANUAL OF PATENT EXAMINING PROCEDURE, SECTION 2001.05

### 2001.05 Materiality Under 37 CFR 1.56(a) [R-2]

Subsection 1.56(a) provides,

> "All such individuals have a duty to disclose to the Office information they are aware of which is *material to the examination* of the application (emphasis added)."

"Material" connotes something more than a trivial relationship. It appears commonly in court opinions. Subsection 1.56(a) elucidates,

> "Such information is material where there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent."

This sentence paraphrases the definition of materiality used by the Supreme Court in TSC Industries v. Northway, 426 U.S. 438, 48 L.Ed. 2d 757, 96 S.Ct. 2126, 44 U.S.L.W. 4852 (1976). Although in that case the court was concerned with rules promulgated by the Securities and Exchange Commission, the Court's articulation of materiality is believed consistent with the prevailing concept that has been applied by lower courts in patent cases.

The definition of materiality in §1.56 has to be interpreted in the context of patent law rather than securities law. Principles followed by courts in securities cases should not be translated to patent cases automatically. It is noteworthy, however, that in formulating the definition of materiality in TSC Industries the Supreme Court noted that the standard of materiality should not be so low that persons would be "subjected to liability for insignificant omissions or misstatements," or so low that the fear of liability would cause management "simply to bury the shareholder in an avalanche of trivial information a result that it is hardly conducive to informed decision making."

Although the third sentence of §1.56(a) refers to decision of an examiner, the duty of disclosure applies in the same

manner in the less common instances where the official making a decision on a patent application is someone other than an examiner, e.g., a member of the Board of Patent Interferences or the Board of Appeals. This is implicit in the duty "of candor and good faith" toward the "Office" that is specified in the first sentence of §1.56(a).

The Court in Norton v. Curtiss, 433 F.2d 779, 167 USPQ 532, 544 (C.C.P.A. 1970) characterized "materiality" as being of "critical concern;" and indicated,

> "[I]n patent cases, materiality has generally been interpreted to mean that if the Patent Office had been aware of the complete or true facts, the challenged claims would not have been allowed."

However, the court then indicated at page 545 of the USPQ citation its concern that "materiality" not be defined too narrowly by stating that

> "the above test cannot be applied too narrowly if the relationship of confidence and trust between applicants and the Patent Office is to have any real meaning. Findings of materiality should not be limited only to those situations where there can be no dispute that the true facts, or the complete facts, if they had been known, would most likely have prevented the allowance of the particular claims at issue or alternatively, would provide a basis for holding those claims invalid."

* * * * *

> "It is our view that a proper interpretation of the "materiality" element of fraud in this context must include therein consideration of factors apart from the objective patentability of the claims at issue, particularly (where possible) the subjective considerations of the examiner and the applicant. Indications in the record that the claims at issue *would* not have been allowed but for the challenged misrepresentations must not be overlooked due to any certainty on the part of the reviewing tribunal that the claimed invention, viewed objectively, *should* have been

patented. If it can be determined that the claims would *not* have been allowed *but for* the misrepresentation, then the facts were material regardless of their effect on the objective question of patentability."

Other courts have also treated the question of "materiality." Thus, in In re Multidistrict Litigation Involving Frost Patent, 185 USPQ 729, 741 (D.Del. 1975), the court characterized the question of "materiality" as follows:

"Some variation of the so-called "but for" test has appeared in nearly every patent fraud case.

* * * * *

"In other words, a finding of fraud is warranted if, but for the misconduct of the patent applicant, the patent would not properly have issued. This is what has been referred to as an "objective but for test".

* * * * *

"The second "but for" test is the so-called "subjective test". This test requires a court to examine the effect which fraudulent representations had upon the examiner. If misrepresentations caused the examiner to issue the patent, then this kind of "but for fraud" will be found.

* * * * *

"The final "but for" test has been labeled "the but it may have" test, i.e., courts look to whether the misrepresentations made in the course of the patent prosecution may have had an effect on the examiner.

* * * * *

"Hence, in this Circuit, a misrepresentation which makes it "impossible for the Patent Office fairly to assess [the] application against the prevailing statutory criteria . . . will, given the requisite intent, lead to a finding of invalidity."

## CERTIFICATE OF SERVICE

It is hereby certified that true and correct copies of this PETITION FOR WRIT OF CERTIORARI have been served upon attorneys for respondent on November 29, 1982, by mailing the copies thereof, contained in sealed envelopes, first-class postage prepaid, addressed to said attorneys as follows:

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